

*IN THE UNITED STATES PATENT AND TRADEMARK OFFICE*

Applicant: Osamu HONMOU et al.

Title: INTERNALLY ADMINISTERED THERAPEUTIC AGENTS FOR CRANIAL NERVE  
DISEASES COMPRISING MESENCHYMA CELLS AS AN ACTIVE INGREDIENT  
(As Amended)

International Appl. No.: PCT/JP2004/009386

International Filing Date: 6/25/2004

Examiner: Unassigned

Art Unit: Unassigned

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §1.56

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

RELEVANCE OF EACH DOCUMENT

The documents being cited in the attached PTO/SB/08 were cited as being relevant during the prosecution of the corresponding international application. A copy of the International Search Report is attached setting forth the portion of the documents considered relevant by the examiner. A copy of the cited references listed in the Search Report are not being submitted herewith.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date Dec. 22, 2005

By Stephen B. Maebius

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10/562202  
MODIFIED PTO/SB/08 (08-00)Approved for use through 10/31/2002. OMB 0651-0031  
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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

Date Submitted: December 23, 2005

(use as many sheets as necessary)

Sheet	1	of	2	Application Number	Unassigned
				Filing Date	December 23, 2005
				First Named Inventor	Osamu HONMOU
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	033873-0108

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			

## U.S. PATENT APPLICATION DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
	A1		JP 2004-544234 A		12/24/2002		
	A2		WO 01/66698 A1		9/13/2001		
	A3		WO 03/25167 A2		3/27/2003		

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A4	DATABASE BIOSIS ON STN, (Last Updated on Stn: 6/19/2003) abstract no. 200300283245 & S. IIHOSHI et al., "Intravenous administration of autologous bone marrow cells repairs the ischemic lesions in the rat middle cerebral artery occlusion model", Society for Neuroscience Abstract Viewer & Itinerary Planner, (2002), vol. 2002, abstract no. 237.8., <a href="http://sfn.scholarone.com">http://sfn.scholarone.com</a>	
	A5	D. LU et al., "Adult bone marrow stromal cells administered intravenously to rats after traumatic brain injury migrate to brain and improve neurological outcome", Neuroreport, 2001, vol. 12, No. 3, pp. 559-563.	
	A6	J. CHEN et al., "Therapeutic benefit of intravenous administration of bone marrow stromal cells after cerebral ischemia in rats", Stroke, 2001, Vol. 32, No. 4, pp. 1005-1011.	
	A7	K. CHU et al., "Human neural stem cells can migrate, differentiate and integrate after intravenous transplantation in adult rats with transient forebrain ischemia", Neurosci. Lett., 6/5/2003, Vol. 343, No. 2, pp. 129-133.	
	A8	Y. AKIYAMA et al., "Remyelination of the spinal cord following intravenous delivery of bone marrow cells", Glia., (2002), Vol. 39, pp. 229-236.	

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	A9	A. MAHMOOD et al., "Treatment of traumatic brain injury in female rats with intravenous administration of bone marrow stromal cells", Neurosurgery, 2002, vol. 49, no. 5, pp. 1196-1203.	
	A10	DATABASE MEDLINE ON STN, (2002), abstract no. 2002333228 & D. LU et al., "Intravenous administration of human umbilical cord blood reduces neurological deficit in the rat after traumatic brain injury", Cell Transplant. (2002), Vol. 11, No. 3, pp. 275-281.	
	A11	DATABASE BIOSIS ON STN, (2001), abstract no. 200100547979 & Y. AKIYAMA et al., "Remyelination of spinal cord axons by intravenous delivery of bone marrow cells", Society for Neuroscience Abstracts, 2001, Vol. 27. No. 2, pg. 1562.	
	A12	DATABASE BIOSIS IN STN, (2003), abstract no. 200300315449 & P. LU et al., "Transplantation of bone marrow stromal cells (MSCS) and BDNF-transducer MSCS promotes robust axonal growth after spinal cord injury", Society for Neuroscience Abstract Viewer & Itinerary Planner, 2002, Vol. 202, abstract no. 634.11 <a href="http://sfn.scholarone.com">http://sfn.scholarone.com</a> .	
	A13	MA KEANE-MOORE et al., "Human mesenchymal stem cells can be genetically modified to function as antigen presenting cells", Blood, (1998), Vol. 92, No. 10, suppl. 1, part 1 to 2, pg. 338A, Abstract #1388.	

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